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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,087	01/09/2004	Reinhardt A. Rosson	3161-20-C1-1	8504

22442 7590 06/13/2006

SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/755,087	ROSSON ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11-13,15,16,19-21,24,25,27 and 32-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,11-13,15,16,19-21,24,25,27 and 32-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[2] Claims 1, 11-13, 15-16, 19-21, 24-25, 27, and 32-39 are pending in the application.

[3] Applicant's preliminary amendment to the specification and the claims, filed on 8/23/2004, is acknowledged. The claim listing filed on 8/23/2004 replaces all prior versions and listings of the claims.

[4] Receipt of an information disclosure statement, filed on 11/19/2005, is acknowledged.

Election/Restrictions

[5] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 11, 13, 15-16, 19-21, 25, drawn to an isolated protein comprising SEQ ID NO:42, classified in class 435, subclass 233.

II. Claims 1, 11-13, 15-16, 19-21, 25, drawn to an isolated protein comprising SEQ ID NO:61, classified in class 435, subclass 233.

III. Claims 24, drawn to an isolated antibody that binds to a protein comprising SEQ ID NO:42, classified in class 530, subclass 389.7.

IV. Claims 24, drawn to an isolated antibody that binds to a protein comprising SEQ ID NO:61, classified in class 530, subclass 389.7.

V. Claims 27, 32, and 34-39, drawn to a method for producing CLA using a protein comprising SEQ ID NO:42, classified in class 435, subclass 134.

VI. Claims 27 and 32-39, drawn to a method for producing CLA using a protein comprising SEQ ID NO:61, classified in class 435, subclass 134.

[6] The inventions are distinct, each from the other because:

[7] Inventions I and II are related as being linoleate isomerase polypeptides. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the polypeptides are mutually exclusive and have a different design as each of the polypeptides of Groups I and II is structurally distinct neither of the polypeptides of Groups I or II would render the other obvious to one of ordinary skill in the art.

[8] Inventions III and IV are related as being antibodies that bind to a linoleate isomerase polypeptide. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the antibodies are mutually exclusive and have a

different design as each of the antibodies of Groups III and IV binds a structurally distinct protein, *i.e.,* SEQ ID NO:42 or 61, and neither of the antibodies of Groups III or IV would render the other obvious to one of ordinary skill in the art.

[9] Inventions V and VI are related as being methods of using a linoleate isomerase polypeptide. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods are mutually exclusive and have a different design as each of the methods of Groups V and VI uses a different linoleate isomerase polypeptide and neither of the methods of Groups V or VI would render the other obvious to one of ordinary skill in the art.

[10] The polypeptide of group I and the antibody of group III or the polypeptide of group II and the antibody of group IV are patentably are patentably distinct for the following reasons: While the polypeptide of group I and the antibody of group III or the polypeptide of group II and the antibody of group IV are polypeptides, in this instance the polypeptide of groups I-II is a single chain molecule that functions as an enzyme, whereas the polypeptide of groups III-IV encompasses antibodies including IgG which comprises 2 heavy and light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group III or the polypeptide of group II and the antibody of

group IV are structurally distinct molecules; any relationship between the polypeptide of group I and the antibody of group III or the polypeptide of group II and the antibody of group IV is dependent upon the correlation between the scope of the polypeptides that the antibody or binding partner binds and the scope of the antibodies or binding partners that would be generated using the polypeptide. In this case, the polypeptide of groups I-II is a large molecule which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of groups III-IV is defined in terms of its binding specificity to a small structure within, *e.g.,* SEQ ID NO:42 or 61. Thus the polypeptide of groups I-II would result in the production of antibodies outside the scope of groups III-IV. Therefore the polypeptide of group I and the antibody of group III or the polypeptide of group II and the antibody of group IV are patentably distinct. Furthermore, searching the polypeptide of group I and the antibody of group III or the polypeptide of group II and the antibody of group IV together would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody each require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibody of groups III-IV. Furthermore, antibodies which bind to an epitope of a polypeptide of groups I-II may be known even if a polypeptide of groups I-II is novel. Similarly, an amino acid sequence search for fragments of the polypeptide is required to determine the novelty and nonobvious of the antibodies of groups III-IV, however such a search is not required or sufficient to identify all of the

polypeptides of groups I-II. In addition, the technical literature search for the polypeptide of groups I-II and the antibody of groups III-IV are not coextensive, e.g., antibodies or binding partners may be characterized in the technical literature prior to discovery of or sequence of their binding target.

[11] The polypeptide of Group I is unrelated to the antibody of Group IV and the polypeptide of Group II is unrelated to the antibody of Group III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the polypeptide of Group I does not bind to the antibody of Group IV and the polypeptide of Group II does not bind to the antibody of Group III.

[12] The polypeptide of Group I and the method of Group V or the polypeptide of Group II and the method of Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case CLA can be produced synthetically and the polypeptide of Group I or II can be used as an antigen in the production of the antibody of Group III or IV, respectively.

[13] The polypeptide of Group I is unrelated to the method of Group VI and the polypeptide of Group II is unrelated to the method of Group V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In

the instant case, the polypeptide of Group I is neither made nor used by the method of Group VI and the polypeptide of Group II is neither made nor used by the method of Group V.

[14] The antibodies of Groups III-IV are unrelated to the methods of Groups V-VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the antibodies of Groups III-IV are neither made nor used by the methods of Groups V-VI.

[15] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I-VI are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Each of the inventions requires a separate patent and non-patent literature and/or sequence search and thus, co-examination of the inventions of Groups I-VI would be a serious burden on the examiner.

[16] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[17] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

[18] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

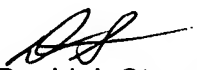
and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656